

DOCKET NO.: OMOR-0012
Application No.: Not yet known

PATENT

AP20 Rec'd PCT/PTO 22 JUN 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Takaharu HAMADA**Confirmation No.: **not yet assigned**Application No.: **not yet known**Group Art Unit: **not yet known**Filing Date: **not yet known**International Application No.: **PCT/JP2005/019565** Examiner: **not yet assigned**International Filing Date: **December 27, 2004**For: **SAFETY TEST SUPPORT SYSTEM,
METHOD AND PROGRAM**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Enclosed is a copy of the Information Disclosure Citation Form together with copies of the documents cited on that form. It is respectfully requested that the cited documents be considered and that the enclosed copy of the Information Disclosure Citation Form be initialed by the Examiner to indicate such consideration and a copy thereof returned to applicant(s).

Pursuant to 37 C.F.R. § 1.97(g) and (h), the submission of this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed as an admission that the information cited in this statement is material to patentability.

The following are comments on any non-English-language references pursuant to Rule 98:

Ueno et al. shows a computer validation system, for analyzing flow and conducting cleanliness evaluations at a pharmaceutical plant, in order to improve manufacturing purities in keeping with the increasing demands of GMP (Good Manufacturing Practices).

However, the above reference does not show the advantageous features of the present invention, involving executing inspection scenario programs, according to multiple inspection

scenarios that are respectively associated with various multiple applications, in conjunction with detecting the degree of any system changes, and repeated, periodic user authentications, to thereby vastly reduce the workload and operating costs of validations and improve strict GLP (Good Laboratory Practices) compliance

Pursuant to 37 C.F.R. § 1.97, this Information Disclosure Statement is being submitted under one of the following (as indicated by an "X" to the left of the appropriate paragraph):

X 37 C.F.R. §1.97(b).

☐ 37 C.F.R. §1.97(c). If so, then enclosed with this Information Disclosure Statement is one of the following:

☐ A certification pursuant to 37 C.F.R. §1.97(e) or

☐ A check for \$_____ for the fee under 37 C.F.R. § 1.17(p).

☐ 37 C.F.R. § 1.97(d). If so, then enclosed with this Information Disclosure Statement are the following:

- (1) A certification pursuant to 37 C.F.R. §1.97(e)*;
- (2) A petition requesting consideration of the Information Disclosure Statement; and
- (3) A check for \$_____ for the fee under 37 C.F.R. §1.17(p) for submission of the Information Disclosure Statement.

*37 C.F.R. 1.97 (d) includes the following Certification pursuant to 37 C.F.R. 1.97 (e):

____ That each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to filing this statement.

____ That no item of information contained in the information statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned attorney after making reasonable inquiry, was known to any individual designated in 1.56(c) more than three months prior to filing of this statement.

If there are any additional charges, please charge Deposit Account No. 23-3050.

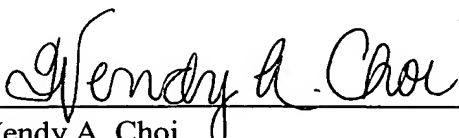
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10/28/06
iAP20 Rec'd PCT/PTO 22 JUN 2006

Should the Examiner have any questions or comments regarding the Information Disclosure Statement, the Examiner is invited to telephone the undersigned at the number listed below.

Date: June 22, 2006


Wendy A. Choi
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Approved for use through 07/31/2006. OMB 0651-0031

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Complete if Known

(Use as many sheets as necessary)

Sheet	1	of	3
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Application Number	Not known
Filing Date	10/584167
First Named Inventor	Not known
Art Unit	Not known
Examiner Name	Now known
Attorney Docket Number	OMOR-0012

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		JP07-11325	04.25.1995	Lion Corp		✓
		JP 10-275093	10.13.1998	Hitachi Software Eng Co Ltd		✓
		JP 2001-350650	12.21.2001	NTT Comware Corp.		✓
		JP2001-116744	04.27.2001	KK H&T et al.		✓
		JP05-094298	04.16.1993	NEC Hokuriku Software Co., Ltd.		✓
		JP07-013809	01.17.1995	NEC Corp.		✓

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND

TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Complete if Known

Application Number	Not known
Filing Date	Herewith
First Named Inventor	Not known
Art Unit	Not known
Examiner Name	Now known
Attorney Docket Number	OMOR-0012

Sheet	2	of	3
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Examiner Signature		Date Considered	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	Not known 10/584167
		Filing Date	Herewith
		First Named Inventor	Takaharu HAMADA
		Art Unit	Not known
		Examiner Name	Not known
Sheet 3 of 3	Attorney Docket Number	OMOR-0012	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		SEI (Kiyoshi) MURAKAMI et al, Tokushu Iyaku hin Seizogyo ni Okeru keisoku Seigyo Joho System:Iyaku hin Keisoku Seigyo System to Senjo Variation, Hitachi Hyouron, 1996,04,01, Vol. 78 No. 4, Japan	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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